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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,243	12/21/2000	Narendra Parikh	JBP514	8350

7590 05/20/2005

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/745,243	PARIKH ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8-11,13,14,16-22,24-36 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8-11,13,14,16-22,24-36 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/19/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6,8-11,13,14,16-22,24-36 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2-53271 in view of Friend et al. (US Pat. 6,139,865), CA 2068366 and Norling et al. (US Pat. 5,958,458).

JP 2-53271 is cited for the same reasons as the prior Office Actions and the same is incorporated herein.

Friend et al. disclose the use of ethyl cellulose, cellulose acetate phthalate and/or hydroxypropylmethyl cellulose phthalate and the like for effective taste masking of drugs (Column 7, lines 22-39). It is taught that the microcapsules provide dissolution of at least about 90% at 45 minutes (Column 8, lines 36-66). It is taught that the particle size of the microcapsules will be in the range of a few microns up to about 1000 microns or more, with particle sizes in the approximately 30 microns to 800 microns, and the particles sizes in the range of approximately 40 microns to 250 microns particularly preferred and that those skilled in the are will recognize that the components of the microcapsules, the relative quantities of the drug and polymeric coating material, the size of the microcapsules and other parameters, can be easily varied to provide of different degrees of taste masking and various release profiles (Column 8, lines 31-43).

CA 2068366 disclose that ethyl cellulose is a water-insoluble polymer and that cellulose acetate phthalate and hydroxypropylmethyl cellulose phthalate are enteric polymers (Pg. 8, lines 26-33, Pg. 9, lines 30-38).

Norling et al. discloses a particle having two or more layers of coating, including film coatings and modified release coatings where the coating provides desired release profile of the active substance or masks the bad-tasting active substances (Column 8, lines 36-68, Column 9, Column 10, lines 1-34).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose examples of enteric and insoluble polymers used in the first coating layer. However, the prior art amply suggests the same as it is known in the art to use water-insoluble and/or enteric polymers, such as ethyl cellulose, cellulose acetate phthalate, cellulose acetate butyrate and/or hydroxypropylmethyl cellulose phthalate and the like for effective taste masking of drugs. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the use of the above polymers would provide taste masking of the drug.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Action and the further reasons below.

Examiner has duly considered Applicant's affidavit, however, it is unclear what was tested. Table A recites HPMC/PEG ratios, however, the amounts of PEG and HPMC do not correspond to the ratios. For example, in Batch 2, 77.9% PEG and 19.4% HPMC results in a HPMC/PEG ratio of 1:4 not 4:1. A similar problem exists with respect to batches 1, 3 and 4. As such, since it is not known what ratio was actually tested, the affidavit is insufficient to show unexpected properties.

Examiner makes further observations which Applicant should considered should another affidavit be submitted. The evidence submitted is not commensurate in scope with the claims. The claimed range is about 80:20 to 20:80 and includes any film forming polymer and any anti-grit agent. Whereas the evidence submitted only compared the 80:20 or 20:80 ratio of film forming polymer to anti-grit agent and only tested HPMC with PEG. See In re Clemens, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at "elevated temperatures" using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also In re Peterson, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); In re Grasselli, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalyst containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims.). Further, to establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. In re Hill, 128 USPQ 197 (CCPA 1960).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
May 13, 2005

JOHN PAK
PRIMARY EXAMINER
GROUP 1600